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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,723	03/01/2002	Martin Caldwell	1890-0019	1585

7590 05/08/2003

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EXAMINER
PHANIJPHAND, GWEN G

ART UNIT	PAPER NUMBER
3731	8

DATE MAILED: 05/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/936,723	Applicant(s) CALDWELL ET AL.	
	Examiner Gwen Phanijphand	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-8* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/01/2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections – 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 3, 4, and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,984,564 to Yuen.

Regarding claim 1, Yuen discloses a device for use in minimally invasive surgery using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patient's body (col. 1, ll. 14-24). The device has a body cavity engagement means for insertion into the incision to locate the device in position, a fixing means for attaching the device to a patient's skin (Fig. 2: element 12), and a sleeve connected between the body cavity engagement means and the fixing means defining an access port (Fig. 2: element 16). The device includes a sealing means (Fig. 2: element 16), operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position (col. 4, ll. 34-52). The inflatable cuff, 16, is made up of pockets that are inflatable and provide an opening within the device. In Fig. 3, the sealing means is provided by an inflatable first seal for engaging and retracting the incision (element 34: "outer wall") and a second inflatable seal (element 32: "inner wall") for sealing the lumen of the tube or sleeve bore (col. 4, ll. 28-36).

Regarding claim 3, Yuen discloses in Fig. 2 a device in which the body cavity engagement means (14) is provided by a distal ring formed for insertion into the incision.

Regarding claim 4, Yuen discloses in Fig. 2 a device in which the fixing means (12) is provided by a proximal ring for engaging with a patient's skin.

Regarding claim 6, Yuen discloses in Fig. 3 a device in which the first seal (34) is provided by an inflatable bladder extending outwardly from the sleeve on inflation to form a seal with the incision (col. 3, ll. 28-36). As the cuff is inflated, the outer wall (first seal) of the cuff becomes inflated, expands, and forms a seal with the incision (col. 4, ll. 40-44).

Regarding claim 7, Yuen discloses in Fig. 3 a device in which the second seal (32) is provided by an inflatable bladder extending inwardly from the tube or sleeve on inflation that is capable of preventing excessive loss of gas through the access port (col. 3, ll. 28-36). When the cuff is inflated, the inner wall (second seal) expands and is capable of being inflated to prevent loss of gas through the access port (col. 4, ll. 40-44).

Regarding claim 8, Yuen discloses in Fig. 2 a device in which the second seal (32) is operatively connected and mounted within the first seal (34).

2. Claims 1 and 3-8 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,545,179 to Williamson, IV.

Regarding claim 1, Williamson, IV discloses a device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patient's body (Abstract). The device has a body cavity engagement means (Fig. 5: element 40) for insertion into the incision to locate the device in position, a fixing means for attaching the device to a patient's skin (Fig. 5: element 27),

and a sleeve connected between the body cavity engagement means and the fixing means defining an access port (Fig. 5: element 26). The device includes a sealing means (Fig. 5: elements 35 and 34), operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position. The sealing means is provided by an inflatable first seal (35) for engaging and retracting the incision and a second inflatable seal (34) for sealing the lumen of the tube or sleeve bore.

Regarding claim 3, Williamson, IV discloses in Fig. 5 a device in which the body cavity engagement means (40) is provided by a distal ring formed for insertion into the incision. The distal end, 35 and 37 of 34, forms a ring shape and is used for insertion. In Fig. 1, the engagement means (element 23 in this Figure) is shown inserted into the incision.

Regarding claim 4, Williamson, IV discloses in Fig. 5 a device in which the fixing means is provided by a proximal ring (27) for engaging with a patient's skin.

Regarding claim 5, Williamson, IV discloses in Fig. 5 a device in which the proximal ring (27) has an associated connector ring (25) for receiving additional seals or medical instruments.

Regarding claim 6, Williamson, IV discloses in Fig. 5 a device in which the first seal (35) is provided by an inflatable bladder extending outwardly from the sleeve on inflation to form a seal with the incision (col. 5, ll. 58-67; col. 6, ll. 1-3). The outer inflatable sleeve, 35, comprises of element 40, which is inflated and seals the incision.

Regarding claim 7, Williamson, IV discloses in Fig. 5 a device in which the second seal (34) is provided by an inflatable bladder extending inwardly from the tube or sleeve on inflation

that is capable of preventing excessive loss of gas through the access port (col. 2, ll. 60-64; col. 5, ll. 63-67). The second seal is the inflation of the "inner channel" or "inner wall of the central channel" that compresses and provides a seal.

Regarding claim 8, Williamson, IV discloses in Fig. 5 a device in which the second seal (34) is operatively connected and mounted within the first seal (35).

3. Claims 1, 3, 4, and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,634,937 to Mollenauer et al.

Regarding claim 1, Mollenauer et al. disclose a device for use in minimally invasive surgery using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patient's body (Abstract). In Fig. 17, the device has a body cavity engagement means (61) for insertion into the incision to locate the device in position, a fixing means (60) for attaching the device to a patient's skin, and a sleeve connected between the body cavity engagement means and the fixing means defining an access port. In Fig. 12, the device includes a sealing means (49, 50), operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position. The sealing means is provided by an inflatable first seal (50) for engaging and retracting the incision and a second inflatable seal (49) for sealing the lumen of the tube or sleeve bore (col. 10, ll. 35-38, ll. 54-65).

Regarding claim 3, Mollenauer et al. disclose in Fig. 17 a device in which the body cavity engagement means is provided by a distal ring (61) formed for insertion into the incision. In Fig. 12, the distal end of the balloon is formed by the outer balloon membrane, 50, and the inner

balloon membrane, 49, which both create a ring shape that is inserted into the incision (col. 10, ll. 26-30).

Regarding claim 4, Mollenauer et al. disclose in Fig. 17 a device in which the fixing means (60) is provided by a proximal ring for engaging with a patient's skin. In Fig. 12, the proximal end of the balloon is formed by the outer balloon membrane, 50, and the inner balloon membrane, 49, which both create a ring shape that remains on the skin (col. 10, ll. 30-33).

Regarding claim 6, Mollenauer et al. disclose a device in which the first seal (Fig.12: element 50) is provided by an inflatable bladder extending outwardly from the sleeve on inflation to form a seal with the incision (col. 10, ll. 10-15, 55-60). In Fig. 17 as the balloon is inflated, the first seal expands against the skin and subcutaneous fat (elements 27 and 33)

Regarding claim 7, Mollenauer et al disclose a device in which the second seal (Fig.12: element 49) is provided by an inflatable bladder extending inwardly from the tube or sleeve on inflation to prevent excessive loss of gas through the access port (col. 10, ll. 60-64) .

Regarding claim 8, Mollenauer et al disclose in Fig. 12 a device in which the second seal (49) is operatively connected and mounted within the first seal (50).

Allowable Subject Matter

4. Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made record of and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,033,426 to Kaji
U.S. Patent No. 5,871,474 to Hermann et al.
U.S. Patent No. 5,522,791 to Leyva

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gwen Phanijphand whose telephone number is 703-305-4845. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

GP

GP

April 29, 2003

Gwen Phanijphand
Patent Examiner
Art Unit 3731

Michael J. Milano
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Technology Center 3700